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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | |
|--|----------------|----------------------|---------------------|-------------------|--|
| 09/821,463 | 06/12/2001 | Michel Pagniez | 01076 | 2261 | |
| 23338 7: | 590 06/17/2005 | | EXAM | INER | |
| DENNISON, SCHULTZ, DOUGHERTY & MACDONALD | | | HELMER, G | HELMER, GEORGIA L | |
| 1727 KING ST SUITE 105 | REET | | ART UNIT | PAPER NUMBER | |
| ALEXANDRIA, VA 22314 | | | 1638 | | |

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|--|--|--|--|--|--|
| | 09/821,463 | PAGNIEZ ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Georgia L. Helmer | 1638 | | | | |
| The MAILING DATE of this communication a Period for Reply | appears on the cover sheet with the | correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a it - If NO period for reply is specified above, the maximum statutory perions - Failure to reply within the set or extended period for reply will, by state - Any reply received by the Office later than three months after the may - earned patent term adjustment. See 37 CFR 1.704(b). | N. 1.136(a). In no event, however, may a reply be to reply within the statutory minimum of thirty (30) day od will apply and will expire SIX (6) MONTHS from tute, cause the application to become ABANDON | ays will be considered timely. In the mailing date of this communication. IED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 20 |) April 2005. | | | | | |
| 2a)☐ This action is FINAL . 2b)☒ T | _ · · · _ · · · · · · · · · · · · · · · · · · | | | | | |
| 3) Since this application is in condition for allow | | | | | | |
| closed in accordance with the practice unde | er <i>Ex parte Quayl</i> e, 1935 C.D. 11, 4 | 453 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>16-18,20-27,30-32,36 and 37</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>16-18,20-27,30-32,36 and 37</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and | d/or election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Exam | iner. | | | | | |
| 10) The drawing(s) filed on is/are: a) □ a | ccepted or b) objected to by the | Examiner. | | | | |
| Applicant may not request that any objection to the | he drawing(s) be held in abeyance. Se | ee 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the corr | ection is required if the drawing(s) is o | bjected to. See 37 CFR 1.121(d). | | | | |
| 11) The oath or declaration is objected to by the | Examiner. Note the attached Offic | e Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for forei a)⊠ All b)□ Some * c)□ None of: | gn priority under 35 U.S.C. § 119(a | a)-(d) or (f). | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a l | ist of the certified copies not receiv | ved. | | | | |
| | | | | | | |
| Attachment(s) | 4. □ | (DTO 440) | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) | | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date | | Patent Application (PTO-152) | | | | |
| J.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Office | Action Summary | Part of Paper No./Mail Date 77 | | | | |

Part of Paper No./Mail Date 77

Page 2

Application/Control Number: 09/821,463

Art Unit: 1638

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 April 2005 has been entered.

Status of the Claims

- 2. Claims 16-18, 20-27, 30-32 and 36-37 are pending, and are examined in the instant action.
- 3. All rejections not addressed below have been withdrawn.
- 4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112-2nd

5. Claims 16-18, 20-27, 30-32 and 36-37 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 16-18, 20-27, 30-32 and 36-37

 In 16 (a1) line 2, "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding Application/Control Number: 09/821,463

Art Unit: 1638

regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, more definite language is suggested. The terminology "a DNA sequence" is suggested. Or Applicant may recite the various components of the "gene" desired. All recitations of "gene" are also rejected, and all dependent claims containing this language are also rejected.

In claims 16(d) line 4, and 17(d) line 4, the terms "only containing" need to be changed to "containing only" for clarity.

All claims dependent on these claims are also rejected, for the reasons stated above.

Claim Rejections - 35 USC § 112 -Enablement

6. Claims 16-27, 30-32 and 36-37 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record, as set forth in the Office Action of 20 October 2004. Applicant has made amendments which overcome some of the previous enablement issues, namely the issues of "Agrobacterium rhizogenes containing a vector", and Agrobacterium rhizogenes containing a vector carrying a T-DNA comprising a gene encoding a H202 producing protein...".

Applicant traverses (Response of 20 April 2005, p. 9-10) that the Applicant's have clearly exemplified the present invention, and, citing Example 1.1 and 2, which "are complete working examples". Applicant asserts further that

Application/Control Number: 09/821,463

Art Unit: 1638

the Office has not provided objective reasoning as to why the method could not work with other plants or genes. Applicant further cites various references putatively relevant.

Applicant's traversal is unpersuasive. Previous Office Action's are replete with objective reasonings supporting the Enablement rejection. See Office Action of 23 October 2003, p. 9 especially, and Office Action of 20 October 2004, p. 3-8. Applicant's cited references refer to transformation of specific plants with Agrobacterium rhizogenes, which is only one step of the claimed invention. The invention as a whole is a method comprising transforming, selecting, regenerating, and sorting according to phenotype to obtain desired transgenic plants. The Applicant is encouraged to submit a § 1.132 Declaration from the inventor(s), as attorney's statements re working examples are not probative as evidence.

In response to applicant's argument based upon the age of the Dixon reference, contentions that the reference(s) are old and are not relevant to the state of the art at the time of filing are not persuasive. The general observations of Dixon remain relevant, as evidenced by Hansen (Recent advances in the transformation of plants, Trends in Plant Science, volume 4, No 6, June 1999, pages 226-231, see pages 228, 229 and 230). "Plant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one."

Application/Control Number: 09/821,463 Page 5

Art Unit: 1638

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD Patent Examiner Art Unit 1638 7 June 2005 PRIMARY EXAMINER